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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,565	02/08/2006	Edward L.G. Pryzdial	701826-57320	4718

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David S Resnick
Nixon Peabody
100 Summer Street
Boston, MA 02110-2131

EXAMINER	
BRADLEY, CHRISTINA	

ART UNIT	PAPER NUMBER
1654	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,565	PRYZDIAL, EDWARD L.G.	
	Examiner	Art Unit	
	Christina Marchetti Bradley	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claim 1-4, 20, and 23 drawn to a method of accelerating blood clot dissolution or a pharmaceutical composition comprising anionic phospholipid-binding protein.

II-IV. Claims 1, 3, 4, 5, 6, 10, 11, 14-17, and 20-23, drawn to a method of accelerating blood clot dissolution or a pharmaceutical composition comprising Xaα, Xaβ or Xaγ, respectively.

V-VII. Claims 1, 3, 4, 5, 6, 10, 11, 14-17, and 20-23, drawn to a method of accelerating blood clot dissolution or a pharmaceutical composition comprising Xaα and Xaβ, Xaα and Xaγ, or Xaβ and Xaγ.

VIII. Claims 1, 3, 4, 7, 8, 12-17, and 20-23, drawn to a method of accelerating blood clot dissolution or a pharmaceutical composition comprising Va.

IX-XI. Claim 1, 3, 4, 9, and 20-23, drawn to a method of accelerating blood clot dissolution or a pharmaceutical composition comprising Xaα and Va, Xaβ and Va, or Xaγ and Va, respectively

XII-XXI Claims 18 and 19, drawn to a method for detecting a fibrinolytic potential in a subject comprising measuring the level of Xaα, Xaβ, Xaγ, Va, Xaα and Xaβ, Xaα and Xaγ, Xaβ and Xaγ, Xaα and Va, Xaβ and Va, or Xaγ and Va, respectively.

The inventions listed as Groups I-XXI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the coagulation proteins Xaα, Xaβ, Xaγ, and Va have different structures and functions and therefore lack unity of invention *a priori*.

Inventions II-IV and VIII are related as subcombinations usable together. Inventions V-VII and IX-XI are related to inventions II-IV and VIII as combination/subcombination. The claims are drawn to methods which require administering at least one coagulation protein to accelerate the dissolution of a blood clot. The claims are directed to numerous distinct methods recited in the alternative. The language "at least one coagulation protein" requires that one, two, three, four or five of the five recited coagulation proteins are administered. For example, a method requiring Factor Xaα is distinct from a method requiring Factor Xaβ because the methods have a different mode of operation, do not overlap in scope, and they are not obvious variants of one another (see MPEP 806.05(j)). Each of the coagulation proteins has a distinct chemical structure and function.

The claims encompass many subcombinations which are disclosed as usable together in a single combination and which are also separately usable. For example, consider the following combinations of "one or more" coagulation proteins:

Subcombination (A): Factor Xaα

Subcombination (B): Factor Va

Combination (A+B): Factor Xaα and Factor Va

Each of the combinations of coagulation proteins are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In this case subcombinations (A) and (B) do not overlap in

scope and there is no evidence on the record to suggest that they are obvious variants of one another. The subcombinations are separately usable as evidenced by their presentation in the alternative within the claims. Further, subcombination "A" has separate utility such as in the removal of fusion tags, such as the common histidine tag, from expressed proteins. So, subcombinations (A) and (B) are distinct. See MPEP § 806.05(d).

These subcombinations are also distinct from the combination which comprises them because the combination does not require the particulars of the subcombination as claimed to show novelty or unobviousness and the subcombinations have utility by themselves or in another combination. The fact that the claim encompasses an embodiment which relies on only subcombination (B) is evidence that the details of subcombination (A) are not required for patentability of the combination (A+B), and likewise, the fact that the claim encompasses an embodiment which relies on only subcombination (A) is evidence that the details of subcombination (B) are not required for patentability of subcombination (A+B). The fact that the claim encompasses embodiments which use only subcombination (A) or subcombination (B) is evidence that the subcombinations have utility by themselves.

This example particularly discusses only the combinations (A), (B) and (A+B), but the same analysis could be applied to each of the different subcombinations and combinations set forth in the instant claims.

Invention I is related to inventions XII-XXI. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP §

806.05(j). In the instant case, the inventions as claimed have a materially different design as the method of Group I utilizes anionic phosphor-lipid binding protein and the methods of groups XII-XXI use Factor X or Factor V derivatives or combinations thereof. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions XII-XXI are related to inventions II-XI. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different design as the method of Group XXII measures the level of coagulation proteins and the products of groups X II-XXI are for the administration of coagulation proteins. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

Applicant is required to select a single invention, ie, a single coagulation protein or a single combination of coagulation proteins required for the claimed methods or pharmaceutical compositions. The invention may be a method or pharmaceutical composition involving a single coagulation protein, a combination of more than one coagulation protein but less than all of the disclosed coagulation proteins or a combination of all possible claimed coagulation proteins.

However, an election of a single invention, ie, a method or pharmaceutical composition involving a single coagulation protein or a single combination of coagulation proteins is required. This restriction requirement is predicated on the fact that the methods and pharmaceutical compositions which use different coagulation proteins or different combinations of coagulation proteins do not appear obvious over one another.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of conditions are as follows: thrombosis, platelet hyperactivity, cardiac ischemia, wound, cardiovascular disease, atherosclerosis, or myocardial infarction.

The species of fibrinolytic agents are as follows: plasminogen activator, urokinase, or streptokinase.

The species of thrombin inhibitors are as follows: hirudin, bivalirudin, lepirudin and heparin.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An

argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the conditions involve different patient populations and the fibrinolytic agents and thrombin inhibitors have different chemical structures and therefore lack unity of invention *a priori*..

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Marchetti Bradley whose telephone number is (571) 272-9044. The examiner can normally be reached on Monday-Friday, 8:30 A.M. to 3:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cecilia Tsang/
Supervisory Patent Examiner, Art Unit 1654

/Christina Marchetti Bradley/
Examiner, Art Unit 1654